

## IN THE CLAIMS

1. (currently amended) A method for diagnosing a cancer in a mammal, comprising:

detecting and measuring the hepsin gene copy number in a biological subject obtained from a region of the mammal that is suspected to be precancerous or cancerous, thereby generating data for a test gene copy number; and

comparing the test gene copy number to data for a control gene copy number, wherein a detectable increase in amplification of the gene in the biological subject relative to the control indicates the presence of a precancerous lesion or a cancer in the mammal.

2. (previously presented) The method according to claim 1, wherein the biological subject is ovarian tissue.

3. (previously presented) The method according to claim 1, wherein at least one of the data for the test gene copy number or the data for the control gene copy number are stored in a data storage medium selected from the group consisting of paper, electronic mail, disk, compact disk (CD), digital versatile disk (DVD), memory card, memory chip, ROM, RAM, magnetic optical disk, tape, video, video clip, microfilm, internet, shared network, and shared server.

4-8. (canceled).

9. (currently amended) A method for monitoring the efficacy of a therapeutic treatment regimen in a patient, comprising:

measuring the hepsin gene copy number in a first sample of precancerous or cancer cells obtained from a patient at a first time point in a treatment regimen;

~~administering the treatment regimen to the patient;~~

measuring the hepsin gene copy number in a second sample of precancerous or cancer cells obtained from the patient at a second time point in following administration of the treatment regimen; and

comparing the gene copy number in the first and the second samples, wherein data showing a detectable decrease in the gene copy number levels in the second sample relative to the first sample indicates that the treatment regimen is effective in the patient.

10. (previously presented) The method according to claim 9, wherein the precancerous or cancer cells are obtained from ovarian tissue, prostate tissue, breast tissue, or lung tissue.

11. (previously presented) The method according to claim 9, wherein data representing the hepsin gene copy number in at least one of the first and second samples are stored in a data storage medium selected from the group consisting of paper, electronic mail, disk, compact disk (CD), digital versatile disk (DVD), memory card, memory chip, ROM, RAM, magnetic optical disk, tape, video, video clip, microfilm, internet, shared network, and shared server.

12. (currently amended) A method for diagnosing a breast cancer or a lung cancer in a mammal, comprising:

measuring a test level of hepsin mRNA expression in a biological subject obtained from a region of the mammal that is suspected to be precancerous or cancerous; and

comparing the test level to a control level of hepsin mRNA expression, wherein a detectable increase in the test level relative to the control level indicates the presence of a cancer or precancerous lesion in the mammal.

13. (canceled).

14. (previously presented) The method according to claim 12, wherein data representing at least one of the test and the control levels are stored in a data storage medium selected from

the group consisting of paper, electronic mail, disk, compact disk (CD), digital versatile disk (DVD), memory card, memory chip, ROM, RAM, magnetic optical disk, tape, video, video clip, microfilm, internet, shared network, and shared server.

15-21. (canceled).

22. (currently amended) A method for monitoring the efficacy of a therapeutic treatment regimen in a patient, comprising:

measuring a first expression level of at least one of hepsin mRNA or hepsin protein in a first sample of a biological subject comprising precancerous or cancer cells obtained from a patient at a first time point in a treatment regimen;

~~administering the treatment regimen to the patient;~~

measuring a second expression level of at least one of hepsin mRNA or hepsin protein in a second sample of the biological subject obtained at a second time point in ~~following~~ ~~administration of~~ the treatment regimen; and

comparing the first and second expression levels, wherein a detectable decrease in the second expression level relative to the first expression level indicates that the treatment regimen effectively reduced the number of precancerous or cancer cells in the biological subject.

23. (previously presented) The method according to claim 22, wherein the biological subject is ovarian tissue, prostate tissue, breast tissue, or lung tissue.

24. (previously presented) The method according to claim 22, wherein data representing at least one of the first and second expression levels are stored in a data storage medium selected from the group consisting of paper, electronic mail, disk, compact disk (CD), digital versatile disk (DVD), memory card, memory chip, ROM, RAM, magnetic optical disk, tape, video, video clip, microfilm, internet, shared network, and shared server.

25-32. (canceled).

33. (currently amended) A method for diagnosing a breast cancer in a mammal, comprising:

detecting a test hepsin protein expression level by contacting a biological subject obtained from a region of the mammal that is suspected to be precancerous or cancerous with anti-hepsin antibody; and

comparing the test hepsin protein expression level to a control hepsin protein expression level of a control biological subject, wherein a detectable increase in the test hepsin protein expression level relative to the control hepsin protein expression level indicates the presence of a breast cancer or precancerous lesion in the mammal.

34. (previously presented) The method according to claim 33, wherein the biological subject is breast cancer.

35. (previously presented) The method according to claim 33, wherein data representing at least one of the test and control hepsin protein expression levels are is stored in a data storage medium selected from the group consisting of paper, electronic mail, disk, compact disk (CD), digital versatile disk (DVD), memory card, memory chip, ROM or RAM, magnetic optical disk, tape, video, video clip, microfilm, internet, shared network, and shared server.

36-38. (canceled).

39. (previously presented) The method according to claim 1, wherein the detectable increase in amplification is about 2.5 fold.

40. (previously presented) The method according to claim 9, wherein the detectable decrease in the amplification is about 2.5 fold.

41. (previously presented) The method according to claim 12, wherein the detectable increase in the test level is about 5.0 fold.

42. (previously presented) The method according to claim 22, wherein the detectable decrease in the second expression level is about 5.0 fold.

43. (previously presented) The method according to claim 33, wherein the detectable increase in the test hepsin protein expression level is about 5.0 fold.

44. (previously presented) The method of claim 1 wherein the mammal is a human.

45. (currently amended) The method of claim 9 wherein the patient ~~mammal~~ is a human.

46. (previously presented) The method of claim 12 wherein the mammal is a human.

47. (currently amended) The method of claim 22 wherein the patient ~~mammal~~ is a human.

48. (previously presented) The method of claim 33 wherein the mammal is a human.

49. (previously presented) The method of claim 1 wherein the biological subject is prostate tissue.

50. (previously presented) The method of claim 1 wherein the biological subject is breast tissue.

51. (previously presented) The method of claim 1 wherein the biological subject is lung tissue.

52. (currently amended) A method for diagnosing a cancer in a mammal, comprising:  
determining a hepsin gene copy number in a biological subject obtained from a region of the mammal which is suspected to be precancerous or cancerous, wherein amplification of the hepsin gene copy number relative to a control hepsin gene copy number indicates the presence of cancer or a precancerous lesion in the mammal.

53. (previously presented) The method of claim 52 wherein the mammal is a human.

54. (previously presented) The method of claim 52 wherein the biological subject is ovarian tissue.

55. (previously presented) The method of claim 52 wherein the biological subject is prostate tissue.

56. (previously presented) The method of claim 52 wherein the biological subject is breast tissue.

57. (previously presented) The method of claim 52 wherein the biological subject is lung tissue.

58. (previously presented) The method of claim 52 wherein data representing the hepsin gene copy number is stored in a data storage medium selected from the group consisting of paper, electronic mail, disk, compact disk (CD), digital versatile disk (DVD), memory card, memory chip, ROM, RAM, magnetic optical disk, tape, video, video clip, microfilm, internet, shared network, and shared server.

59. (currently amended) A method for diagnosing a cancer in a mammal, comprising:

determining a first indirect measure of hepsin gene copy number in a biological subject obtained from a region of the mammal that is suspected to be precancerous or cancerous; and

comparing the first indirect measure to a second indirect measure of a control gene copy number in a control biological subject, wherein a detectable change in the first indirect measure relative to the second indirect measure indicates the presence of a precancerous lesion or a cancer in the mammal.

60. (previously presented) The method of claim 59 wherein the first and second indirect measures are determined by real-time quantitative RT-PCR and the detectable change is a detectable decrease.

61. (previously presented) The method of claim 59 wherein the first and second indirect measures are determined by fluorescence *in situ* hybridization (FISH) and the detectable change is a detectable increase.

62. (currently amended) A method for monitoring the efficacy of a therapeutic treatment regimen in a patient, comprising:

determining a first indirect measure of hepsin gene copy number in a first sample of a biological subject comprising precancerous or cancer cells obtained from a patient at a first time point in a treatment regimen;

~~administering the treatment regimen to the patient;~~

determining a second indirect measure of hepsin gene copy number in a second sample of the biological subject obtained at a second time point in ~~following administration of~~ the treatment regimen; and

comparing the first and second indirect measures, wherein a detectable change in the second indirect measure relative to the first indirect measure indicates that the treatment regimen effectively reduced the number of precancerous or cancer cells in the biological subject.

63. (previously presented) The method of claim 62 wherein the first and second indirect measures are determined by real-time quantitative RT-PCR and the detectable change is a detectable decrease.

64. (previously presented) The method of claim 62 wherein the first and second indirect measures are determined by fluorescence *in situ* hybridization (FISH) and the detectable change is a detectable increase.

65. (new) The method of claim 59 wherein the mammal is a human.

66. (new) The method of claim 62 wherein the patient is a human.

67. (new) The method of claim 44 wherein the hepsin gene encodes the amino acid sequence SEQ ID NO:2.

68. (new) The method of claim 67 wherein the hepsin gene comprises the nucleotide sequence SEQ ID NO:1.

69. (new) The method of claim 45 wherein the hepsin gene encodes the amino acid sequence SEQ ID NO:2.

70. (new) The method of claim 69 wherein the hepsin gene comprises the nucleotide sequence SEQ ID NO:1.

71. (new) The method of claim 46 wherein the hepsin gene encodes the amino acid sequence SEQ ID NO:2.

72. (new) The method of claim 71 wherein the hepsin gene comprises the nucleotide sequence SEQ ID NO:1.

73. (new) The method of claim 47 wherein the hepsin gene encodes the amino acid sequence SEQ ID NO:2.

74. (new) The method of claim 73 wherein the hepsin gene comprises the nucleotide sequence SEQ ID NO:1.

75. (new) The method of claim 48 wherein the hepsin gene encodes the amino acid sequence SEQ ID NO:2.



76. (new) The method of claim 75 wherein the hepsin gene comprises the nucleotide sequence SEQ ID NO:1.

77. (new) The method of claim 53 wherein the hepsin gene encodes the amino acid sequence SEQ ID NO:2.

78. (new) The method of claim 77 wherein the hepsin gene comprises the nucleotide sequence SEQ ID NO:1.

79. (new) The method of claim 65 wherein the hepsin gene encodes the amino acid sequence SEQ ID NO:2.

80. (new) The method of claim 79 wherein the hepsin gene comprises the nucleotide sequence SEQ ID NO:1.

81. (new) ) The method of claim 66 wherein the hepsin gene encodes the amino acid sequence SEQ ID NO:2.

82. (new) The method of claim 81 wherein the hepsin gene comprises the nucleotide sequence SEQ ID NO:1.